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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,555	09/25/2000	Veronique M. Braud	SHP-PT059	9366
3624	7590	11/04/2003	EXAMINER	
VOLPE AND KOENIG, P.C. UNITED PLAZA, SUITE 1600 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103			VANDERVEGT, FRANCOIS P	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/555,555	BRAUD ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-23,30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-23,30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a rule 371 continuation of PCT Serial Number PCT/GB98/03686.

Claims 1-19 and 24-29 have been canceled.

New claims 30 and 31 have been added.

Claims 20-23, 30 and 31 are currently pending and are the subject of examination in the present Office Action.

1. In view of Applicant's amendment filed June 16, 2003, only the following grounds of rejection are maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 23 stands rejected under 35 U.S.C. 102(b) as being anticipated by Aldrich et al (1994) Cell 79:649-658, as evidenced by Brooks et al. Journal of Immunology (1999) 162:305-313.

It was previously stated: "Aldrich et al teach a compound consisting of the peptide consisting of the amino acid sequence AMAPRTLTL, which effects the binding of HLA-E to CD94/NKG2 receptors, as evidenced by Brooks et al. Brooks et al teach that the compound AMAPRTLTL associated with HLA-E is recognized by CD94/NKG2A. Therefore, the referenced teachings anticipate the claimed invention."

Applicant's arguments filed June 16, 2003 have been fully considered but they are not persuasive.

Applicant contends that the citation of Brooks is inapplicable under 35 USC § 102 because it is a post-filing date reference and therefore cannot be held as being anticipatory. Applicant is invited to note that the rejection was made over Aldrich, not Brooks - which was cited as an evidentiary reference showing the inherency of the product taught by Aldrich in regard to the claim. Applicant is reminded that

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in certain circumstances, references cited to show a universal fact need not be available as prior art before applicant's filing date. (In re Wilson, 311 F.2d 266, 135 USPQ 442 (CCPA 1962)) Such facts include the characteristics and properties of a material or a scientific truism. See MPEP 2124. Further, while normally only one reference should be used in making a rejection under 35 U.S.C. 102, MPEP 2131.01 states that a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to show that a characteristic not disclosed in the reference is inherent.

MPEP 2131.01(paragraph III): "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (The court went on to explain that "this modest flexibility in the rule that anticipation' requires that every element of the claims appear in a single reference accommodates situations in which the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." 948 F.2d at 1268, 20 USPQ at 1749-50.). Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. Atlas Powder Co. v. IRECO, Inc., 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Two prior art references disclosed blasting compositions containing water-in-oil emulsions with identical ingredients to those claimed, in overlapping ranges with the claimed composition. The only element of the claims arguably not present in the prior art compositions was "sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree." The Federal Circuit found that the emulsions described in both references would inevitably and inherently have "sufficient aeration" to sensitize the compound in the claimed ranges based on the evidence of record (including test data and expert testimony). This finding of inherency was not defeated by the fact that one of the references taught away from air entrainment or purposeful aeration.). See also In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986); Titanium Metals Corp. v. Banner, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985). See MPEP § 2112 - § 2112.02 for case law on inherency. Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP § 2124.

In the present case, Aldrich teaches the peptide consisting of the amino acid sequence AMAPRTLTL as a peptide that is recognized by Qdm-D T cells. While Aldrich does not specifically teach that the peptide has any effect on the binding of HLA-E to CD94/NKG2 receptors, Brooks teaches that the AMAPRTLTL peptide was recognized by CD94/NKG2 receptors when presented in the context of HLA-E. Instant claim 23 is drawn to "[c]ompounds identified by the method according to claim 20, as affecting the binding of HLA-E to CD94/NKG2 receptors." Accordingly, affecting the binding of HLA-E to CD94/NKG2 receptors is an inherent property of the AMAPRTLTL peptide taught by Aldrich as evidenced by the post-filing date teachings of Brooks. There are no differences in the sequence that

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influenced the findings of Brooks and time has no effect on the properties AMAPRTLTL, HLA-E or CD94/NKG2 receptors. Therefore, based upon the evidence of Brooks, the AMAPRTLTL peptide taught by the Aldrich reference would be recognized by persons of ordinary skill as a compound that would be identified by the method of claim 20 and fully satisfies the metes and bounds of claim 23.

3. The following new ground of rejection has been necessitated by Applicant's amendment filed June 10, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 20-23, 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 20 has been amended to recite "cells expressing one of the CD94/NKG2 family of receptors" in lines three and four. Applicant asserts that support for the recitation can be found in the specification at page 3, lines 9-18. However, said passage discloses only that CD94/NKG2A is from the C-lectin superfamily and that CD94 associates with members of the NKG2 family. There is no disclosure, either explicit or implicit, of a distinct family of covalent heterodimeric proteins known as a "CD94/NKG2" family. Accordingly, the recitation constitutes new matter and must be removed. Dependent claims 21-23, 30 and 31 are included in this ground of rejection.

It is suggested that the claim be amended to recite --cells expressing ~~one of the a~~ CD94/NKG2 family of receptors receptor, wherein the NKG2 member is selected from the group consisting of NKG2A, NKG2B, NKG2C, NKG2D, NKG2E, and NKG2F, at the cell surface--, as the NKG2 family is disclosed in the specification as a closed group consisting of the A, B, C, D, E and F molecules.

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Conclusion

3. No claims are allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D. *R*
Patent Examiner
October 30, 2003

Phillip Gambel
PHILLIP GAMBEL, PH.D.
PRIMARY EXAMINER
sent con'ten 1600
9/03/03